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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/975,376	10/11/2001	Chad A. Mirkin	00-713-i12	9821

7590 05/27/2005
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EXAMINER

WILDER, CYNTHIA B

ART UNIT PAPER NUMBER

1637

DATE MAILED: 05/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/975,376

Applicant(s)

MIRKIN ET AL.

Examiner

Cynthia B. Wilder, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 11 March 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 237-240, 243-250, 253-263 and 433-441 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 237-240, 243-250, 253-263 and 433-441 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 9/04 and 10/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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FINAL ACTION

1. This application has been transferred from Examiner Alex Spiegler to Examiner Cynthia Wilder of Art Unit 1637. All future correspondence should be addressed to Examiner Cynthia Wilder whose contact information appears at the end of this Office Action.

2. Applicant's amendment filed March 11, 2005 is acknowledged and has been entered. Claims 237, 243 and 433 has been amended. Claims 241-242, 251-252 and 264-432 have been canceled. Claims 237-240, 243-250, 253-263, and 433-441 are pending. All of the arguments have been thoroughly reviewed and considered but are not found persuasive for the reasons discussed below. Any rejection not reiterated in this action has been withdrawn as being obviated by the amendment of the claims.

This action is made FINAL

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Previous Objections and Rejections

4. The objection to the priority document 60/031,809 is withdrawn in view of Applicant's remarks specifying support for instant invention. The double patenting rejections are withdrawn in view of Applicant's amendment and submission of a proper terminal disclaimer(s). The prior art rejection under 102(b) as being anticipated by Coffey et al is withdrawn in view of Applicant's amendment of the claims. The prior art rejection under 35 USC 102(b) as being anticipated by Chavany et al is withdrawn in view of Applicant's amendment of the claims. The prior art rejection under 35 USC 102(e) directed to claims 237-240, 243-250 and 253-263 as being anticipated by Kossovsky et al and Kausch et al is maintained and discussed below.

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Applicant's Traversal

5. Applicant traverses the rejections on the following ground: Applicant states that the rejection based on Kossovsky et al is inappropriate. Applicant states that the attachment of DNA and RNA to biodegradable nanoparticles for the purpose of transfection. Applicant states that Kossovsky was concerned with protecting the nucleic acid in order to get it into the cell without degradation and loss of biological activity. Applicant states that Kossovsky et al does not teach or suggest that the nanoparticle transfection vectors are stable under hybridization conditions. Applicant states that there is nothing in Kossovsky et al that would teach or suggest that nanoparticles that are stabilized by oligonucleotide attachment at a sufficient surface density. Applicant states Kossovsky does not teach or suggest anything about spacer portions, recognition sequences or diluent oligonucleotides as presently claimed. Applicant states that withdrawal of the rejections based on Kossovsky is in order and respectfully requested.

With regards to Kausch et al.; Applicant contends that the rejection is inappropriate. Applicant states that Kaush teaches various means of attaching biological materials -DNA and protein- to surfaces for the purposes of separation. Applicant contends that the reference does no teach or suggest any nanoparticles having oligonucleotides at a surface density such that nanoparticles are stable under hybridization conditions. Applicant states that Kaush does not deal with gold nanoparticles-oligonucleotide conjugates but with solid surfaces, there can be no disclosure or suggestion of the stabilization of gold nanoparticle particles. Applicant states that moreover, Kausch does not teach or suggest anything about spacer portions, recognition sequences or diluent oligonucleotides as presently claims. Applicant request the rejection be withdrawn.

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In regards to Yguerabide et al, Applicant traverses the rejection and states that the Examiner has alleged teachings of "particle surface density" in the '560 patent. Applicant notes that the Examiner has alleged teachings of "particle surface density". Applicant states that Yguerabide discusses that such particles can be metal-like particles and there is no discussion of any surface density of oligonucleotides present on the surface of the particles anywhere in Yguerabide. Applicant states that Yguerabide does not teach or suggest anything about spacer portions, recognition sequences, or diluent oligonucleotides as presently claims. Applicant states that withdrawal of Yguerabide is in order and respectfully requested.

Examiner's Response

6. All of the arguments filed on 3/11/2005 have been thoroughly reviewed and considered but are not found persuasive for the reasons that follow: In regards to applicant arguments concerning the different uses of the nanoparticles, it is noted that a recitation of an intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963). In this case, the prior art documents teaches the structure of the claimed product as broadly recited therein. The uses as taught in the prior art documents of Kossovsky et al and Kausch et al, such as e.g., protection of the nucleic acid in order to get it into the cell without degradation, or separation purposes, does not alter or effect the structure of the nanoparticles described therein. In regards to Applicant's arguments

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that none of the references teach or suggest the surface densities as described therein, this argument is not convincing because the claims as written do not limit the attachment of the oligonucleotides, and therefore, the claims read on an indirect attachment (e.g., through a moiety) of any types of oligonucleotides as there is no specification of what types of oligonucleotides can be attached and what are the differences between such types. Furthermore, it is noted that the recitation of surface density will be obvious, since stability would likely depend on external condition (e.g., temperature, aqueous conditions, etc.). And presumably as long as the oligonucleotide is attached either directly or indirectly, the oligonucleotides would be present at a surface density sufficient so that the nanoparticles are stable and therefore would include density as recited therein. Additional, since only "at least on" of the oligonucleotides have a sequence complementary to "at least a portion" of the sequence of another nucleic acid or another oligonucleotide, the oligonucleotide can comprise any nucleic acid sequence. In response to Applicant's arguments that none of the references teach wherein the "nanoparticles are stable under "hybridization conditions", it is noted that neither specification nor claims provide a limiting definition for any "hybridization conditions" as it relates to the nanoparticles, thus any binding conditions would be encompassed by the claims. Each of the reference teaches the successful binding or hybridizing of an oligonucleotide either directly or indirectly to nanoparticles. In regards to Applicant's arguments that none of the references teaches "spacer portions, recognition oligonucleotides or diluent oligonucleotide, it is noted that these limitations are only limiting to their specific definitions given in the specification (see page 22). These definitions are sufficiently broad to encompass any nucleic acid sequence. Accordingly, as noted in the previous office action, the claims have been interpreted as being drawn to a nanoparticles

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comprising any oligonucleotides, wherein the oligonucleotide are either directly or indirectly attached to nanoparticles. Applicant's arguments are not sufficient to overcome the prior art rejections. Accordingly, the rejections are maintained.

New Grounds of Rejections

THE NEW GROUNDS OF REJECTIONS WERE NECESSITATED BY APPLICANT'S AMENDMENT OF THE CLAIMS:

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 237-240, 243-250, 253-263 and 433-441 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(a) Claims 237-240, 243-250, 253-263 and 433-441 are indefinite at the recitation of "hybridization condition" or "stringent hybridization conditions" because no hybridization have been specifically defined in the specification and thus it cannot be determine what conditions are required for stabilization of the nanoparticles or for selective discrimination of the nucleic acid target.

Conclusion

9. No claims are allowed. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See

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MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia B. Wilder, Ph.D. whose telephone number is (571) 272-0791. The examiner works a flexible schedule and can be reached by phone and voice mail. Alternatively, a request for a return telephone call may be emailed to cynthia.wilder@uspto.gov. Since email communications may not be secure, it is suggested that information in such request be limited to name, phone number, and the best time to return the call.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER

5/24/05